

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ryan L. et al.

Serial No.: To Be Assigned

Filed: Herewith

For: IMPROVED FLOW CYTOMETRY REAGENT AND SYSTEM
(Divisional of Serial No. 09/747,619 (filed December 22, 2000))

Attorney Docket No.: 1001-015D1

Commissioner of Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Prior to examination of the above-referenced application, please amend the application as follows:

CLEAN VERSION OF AMENDMENTS

In the Claims:

Please cancel claim 1-3, 5-25 and 35-38, and please add new claims 39- 46.
Pending are claims 4, 26-34 and 39-46.

39. (NEW) A method for preparing a sample of fresh human whole blood for cytometric analysis, comprising the steps of:

- a. contacting at least one leukocyte in said fresh blood sample while said fresh blood sample is still fresh with an aqueous reagent that includes:
 - i. a lipoprotein agent for resisting lysing of white blood cells;
 - and
 - ii. an effective amount of an agent for lysing erythrocytes from said fresh blood sample;
 - iii. a physiologically compatible salt; and

- iv. a preservative selected from the group consisting of diazolidinyl urea (DU), imidazolidinyl urea (IDU), an oxazolidine and mixtures thereof;
 - b. labeling said at least one leukocyte with a fluorescent label associated with a known antibody; and
 - c. analyzing said at least one leukocyte with an analytical instrument.
- 40. (NEW) The method of claim 39 wherein:
 - a. said lipoprotein agent is about 5 to about 100/mg/dl;
 - b. said agent for lysing erythrocytes is about 10 to about 300 mg/dl; and
 - c. said preservative is about 1 to about 6gm/dl.
- 41. (NEW) The method of claim 39 wherein said labeling step (b) occurs prior to said contacting step (a).
- 42. (NEW) The method of claim 39 wherein said labeling step (b) occurs after said contacting step (a).
- 43. (NEW) The method of claim 39 wherein said contacting step (a) occurs at least 24 hours prior to said analyzing step (c).
- 44. (NEW) The method of claim 39 wherein said contacting step (a) occurs at least 48 hours prior to said analyzing step (c).
- 45. (NEW) The method of claim 39 wherein said contacting step (a) occurs at least two weeks prior to said analyzing step (c).
- 46. (NEW) A method for preparing a sample of fresh human whole blood for cytometric analysis, comprising the steps of:

- a. contacting at least one leukocyte in said fresh blood sample while said fresh blood sample is still fresh with an aqueous reagent that includes:
- i. about 0.01 to about 5 parts by weight of a high density lipoprotein that is for resisting lysing of white blood cells; and
 - ii. about 0.1 to about 2 parts by weight of an agent for lysing erythrocytes from said fresh blood sample;
 - v. a physiologically compatible salt; and
 - vi. up to about 5 parts by weight of a preservative selected from the group consisting of diazolidinyl urea (DU), imidazolidinyl urea (IDU), an oxazolidine and mixtures thereof;
- b. labeling said at least one leukocyte with a fluorescent label associated with a known antibody; and
- c. analyzing said at least one leukocyte with an analytical instrument by detecting fluorescence indicating the binding of said antibody with a surface antigen of said at least one leukocyte.

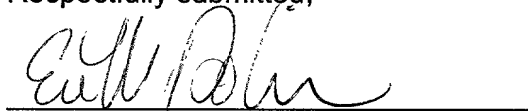
Conclusions

Now pending are claims 4, 26-34 and 39-46. It is believed that all of the claims are in form for allowance and such action is respectfully requested at the earliest possible time. If the Examiner has any questions regarding the present application, the Examiner is requested to contact the undersigned at (248) 593-9900.

If for some reason Applicants have not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent the abandonment of this application, please consider this as a request for an extension for the required time period and/or authorization to charge our Deposit Account No. 50-1097 for any fee which may be due.

Respectfully submitted,

Dated: Feb., 2002



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

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 - ii. an effective amount of an agent for lysing erythrocytes from said fresh blood sample;
 - vii. a physiologically compatible salt; and
 - viii. a preservative selected from the group consisting of diazolidinyl urea (DU), imidazolidinyl urea (IDU), an oxazolidine and mixtures thereof;
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- ci. analyzing said at least one leukocyte with an analytical instrument.

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- a. said lipoprotein agent is about 5 to about 100/mg/dl;
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41. (NEW) The method of claim 39 wherein said labeling step (b) occurs prior to said contacting step (a).

42. (NEW) The method of claim 39 wherein said labeling step (b) occurs after said contacting step (a).

43. (NEW) The method of claim 39 wherein said contacting step (a) occurs at least 24 hours prior to said analyzing step (c).

44. (NEW) The method of claim 39 wherein said contacting step (a) occurs at least 48 hours prior to said analyzing step (c).

45. (NEW) The method of claim 39 wherein said contacting step (a) occurs at least two weeks prior to said analyzing step (c).

46. (NEW) A method for preparing a sample of fresh human whole blood for cytometric analysis, comprising the steps of:

- a. contacting at least one leukocyte in said fresh blood sample while said fresh blood sample is still fresh with an aqueous reagent that includes:
 - i. about 0.01 to about 5 parts by weight of a high density lipoprotein that is for resisting lysing of white blood cells; and
 - ii. about 0.1 to about 2 parts by weight of an agent for lysing erythrocytes from said fresh blood sample;
 - ix. a physiologically compatible salt; and
 - x. up to about 5 parts by weight of a preservative selected from the group consisting of diazolidinyl urea (DU), imidazolidinyl urea (IDU), an oxazolidine and mixtures thereof;
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